(c) Retention, dispensing, promotion, or advertisement of drug products by a licensee of the Board of Pharmacy, either at their business premises or at any separate storage facility after notification of their contraband status, shall constitute a direct and immediate danger to the public health and safety and will be good and sufficient cause for the suspension or revocation of any license issued by the Board of Pharmacy for knowingly retaining, dispensing, promoting, or advertising any drug products which are contraband under this regulation.

This suspension or revocation would occur only after proper hearings are held by the Board of Pharmacy. (10/14/81, Revised 6/20/91)

07-02: COMPOUNDING

07-02-0001—STANDARDS FOR COMPOUNDING AND DISPENSING STERILE PRODUCTS

The purpose of this regulation is to provide standards in the conduct, practices, and operations of a pharmacy preparing and dispensing products requiring sterility, such as injectables, ophthalmics, and inhalants.

Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of a commercially available FDA-approved drug product is generally prohibited. However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available based on documentation provided by the prescribing physician of a patient specific medical need (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The recommended methodology for documenting unavailability is to print the screen of wholesalers showing back-ordered, discontinued, or out-of-stock items. This or similar documentation must be available when requested by the Board.

Except for those products where stability prohibits advanced compounding, all products dispensed by the pharmacy shall be in a form ready for administration, except in health care facilities where medications may be provided as demanded by policies and procedures.

Pharmacies and pharmacists dispensing sterile products shall comply with all applicable federal, state, and local law and regulation concerning pharmacy and also these additional rules:

(a) Guidelines for preparation of sterile products will be based on the distinction of sterile products as either low-risk, medium-risk or high-risk products.

(1) Sterile products compounded under all of the following conditions are considered low-risk sterile products:

(A) The finished products are compounded with aseptic manipulations entirely within a Class 100 environment or better air quality using only sterile ingredients, products, components, and devices.

(B) The compounding involves only transfer, measuring, and mixing manipulations with closed or sealed packaging systems that are performed promptly and attentively.

(C) Manipulations are limited to aseptically opening ampuls, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices and packages of other sterile products.

(D) For a low-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods: before administration, the sterile products

are exposed for no more than forty-eight (48) hours at controlled room temperature, fourteen (14) days at two (2) to eight (8) degrees centigrade, and forty-five (45) days in solid frozen state atnegative twenty (–20) degrees centigrade or colder, while properly stored.

(2) When sterile products compounded aseptically under low-risk conditions, and one or more of the following conditions exists, such products are considered medium-risk sterile products:

(A) Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile product that will be administered either to multiple patients or to one patient on multiple occasions.

(B) The compounding process includes complex aseptic manipulations other than the single-volume transfer

(C) The compounding process requires unusually long duration, such as that required to complete the dissolution or homogeneous mixing.

(D) The sterile products do not contain broad-spectrum bacteriostatic substances, and they are administered over several days.

(E) For a medium-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods: before administration, the sterile products are exposed for no more than thirty (30) hours at controlled room temperature, seven (7) days at two (2) to eight (8) degrees centigrade, and forty-five (45) days in solid frozen state at negative twenty (–20) degrees centigrade or colder, while properly stored.

(3) Sterile products compounded under any of the following conditions are considered high-risk sterile products:

(A) Nonsterile ingredients are incorporated, or a nonsterile device is employed before terminal sterilization

(B) Sterile ingredients, components, devices, and mixtures are exposed to air quality inferior to a Class 100 environment. This includes storage in environments inferior to a Class 100 environment of opened or partially used packages of manufactured sterile products that lack antimicrobial preservatives.

(C) Nonsterile preparations are exposed no more than 6 hours before being sterilized.

(D) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.

(E) For a high-risk preparation, in the absence of passing a sterility test, the storage periods shall not exceed the following time periods: before administration, the sterile products are exposed for no more than twenty-four (24) hours at controlled room temperature, three (3) days at two (2) to eight (8) degrees centigrade, and forty-five (45) days in solid frozen state at negative twenty (–20) degrees centigrade or colder, while properly stored.

~~(1) Low-risk sterile products are those products that meet the following characteristics:~~

(A) ~~The finished product is compounded with commercially available, sterile equipment (e.g. syringes, vials, needles.)~~

(B) ~~Preparation involves basic aseptic manipulations promptly executed (completion of product occurs without interruption.)~~

(C) ~~Closed system transfers are used in which the container closure system remains essentially intact throughout the process, compromised only by penetration of a needle~~

~~or other device used to withdraw the product. (Ampules will be considered closed systems.)~~

(D) ~~Individual products prepared upon receipt of a patient prescription order.~~

(E) ~~Quantities of 48 hours or less and expiration times of 72 hours or less.~~

(2) ~~High-risk sterile products are those products that meet any of the following characteristics:~~

(A) ~~Compounding involves preparation over a prolonged period of time; or~~

(B) ~~Products used are non-sterile; or~~

(C) ~~Batch preparation of large quantities are performed in anticipation of prescription orders; or~~

(D) ~~Epidurals and intrathecals prepared using non-sterile products; or~~

(E) ~~Preparation of parenteral nutrition solutions with expiration dates greater than 48 hours; or~~

(F) ~~Quantities of more than 48 hours and/or expiration times of more than 72 hours, antibiotics and injectables with preservatives (ie: benzyl alcohol, methylparabens) would be exempted and considered as low risk sterile products.~~

(G) ~~Pharmacies and pharmacists preparing low-risk sterile products shall adhere to all of this regulation except section (j), which applies when high-risk sterile products are prepared.~~

(b) Pharmacist requirements:

Any pharmacist in charge who performs or supervises the preparation or sterilization of sterile medications shall:

(1) Have available written policies and procedures for all steps in the compounding of sterile preparations. In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, aseptic technique, quality assurance, expiration dating, and other procedures as needed.

(2) Certify that all participating pharmacists and pharmacy technicians have completed a Board approved training and testing program in sterile product preparation. Documentation of training and testing shall be available for review, by February 30, 2002.

(3) Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians to assure adherence to aseptic procedures.

(c) Pharmacy technician requirements:

Pharmacy technicians participating in the preparation of sterile products shall have completed a Board approved pharmacist supervised training and testing program in sterile product preparation as described in Board regulation 03-00-0006 (b). Documentation of training and testing shall be available.

(d) Work area and equipment:

Any pharmacy dispensing sterile parenteral solutions shall meet or exceed the following requirements:

(1) A separate controlled limited access area (also called a buffer area or buffer room) for compounding sterile solutions, which shall be of adequate space for compounding, labeling, dispensing, and sterile preparation of the medication. This area shall have controlled temperature and humidity. Cleanliness of the area is of critical importance. Drugs and other materials, taken into the limited access area, shall be removed from cardboard and other particle generating materials before being taken into the area.

(2) The controlled limited access area shall have a certified and inspected Class100 environment. Such an environment exists inside a certified laminar airflow hood (clean room, biological safety cabinet or other barrier isolator meeting Class 100 requirements)

used for the preparation of all sterile products. The Class 100 environment device or area is to be inspected and certified yearly. Barrier isolator workstations are closed systems and are not as sensitive to their external environment as laminar airflow equipment. It is recommended to place them in a limited access area with cleaning and sanitizing in the surrounding area on a routine basis.

(3) Hazardous drugs shall be prepared within a certified Class 11, Type A (exhaust may be discharged to the outdoors) or Class 11, Type B (exhaust may be discharged to the outdoors) laminar flow biological safety cabinet. The Class 11, Type B can be obtained with a "bag in-bag out" filter to protect the personnel servicing the cabinet and facilitate disposal. When preparing cytotoxic agents, gowns and gloves shall be worn. All new construction, and those undergoing renovation requiring the moving of existing hoods used in the preparation of cytotoxic drugs, shall exhaust the hood to the outdoors, unless the Board of Pharmacy grants an exception. The cabinet of choice is a Class 11, Type B. For the purpose of this regulation, hazardous drugs shall be defined as agents that exhibit characteristics of genotoxicity, carcinogenicity, teratogenicity, or evidence of serious organ or other toxicity at low doses.

(4) The area shall be designed to avoid excessive traffic and airflow disturbances.

(5) The area shall be ventilated in a manner not interfering with laminar flow hood conditions.

(6) Daily procedures must be established for cleaning the compounding area.

(e) Storage:

All pharmacies preparing and dispensing sterile products must provide:

(4) Adequate controlled room temperature storage space for all raw materials.

(5) Adequate storage space for all equipment. All drugs and supplies shall be stocked on shelving above the floor.

(6) Adequate refrigerator storage space for compounded solutions, with routinely documented temperatures. Temperature ranges required are 36-46° F or 2-8° C.

(7) Adequate freezer storage space if finished products are to be frozen (e.g. reconstituted antibiotics.) There shall be a procedure to routinely document temperatures.

(f) Labeling:

In addition to regular labeling requirements, the label shall include:

(1) Parenteral products shall have the rate of infusion when applicable.

(2) Expiration date (Policies and procedures shall address label change procedures as required by physician orders.)

(3) Storage requirements or special conditions.

(4) Name of ingredients and amounts contained in each dispensing unit.

(5) All products dispensed to outpatients, and removed from the site of preparation for administration different than the site of preparation, shall have label information as required by state law.

(g) Shipping:

(1) Policies and procedures shall assure product stability during delivery.

(2) Pharmacy must assure ability to deliver products within an appropriate time frame.

(h) Home patient care services:

The pharmacist in charge of the pharmacy dispensing sterile parenteral solutions shall provide the following or assure that they are provided prior to providing medications.

(1) The pharmacist must assure that the patient is properly trained if self-administering.

(2) In situations where a pharmacy or pharmacist employs a nurse to administer medications, the pharmacist in charge must:

(A) Employ a registered nurse.
(B) Assure that proper records are maintained in compliance with laws and regulations.
(C) Make these records available to inspectors from appropriate agencies.

(3) 24-hour service shall be assured by the pharmacy.

(4) Pharmacists shall recommend and monitor clinical laboratory data as requested.

(5) Side effects and potential drug interactions should be documented and reported to the physician.

(6) Patient histories and therapy plans should be maintained.

(i) Destruction of cytotoxic drugs:

Any pharmacy providing cytotoxic drugs shall establish procedures assuring the return and proper destruction of any unused radioactive or cytotoxic drugs or other hazardous material (destruction containers for needles).

In every instance, the pharmacist in charge shall monitor the delivery, storage, and administration records of medications dispensed from his/her pharmacy.

(j) When preparing high-risk sterile products, the pharmacist in charge is responsible for making sure the above procedures, in addition to the following, shall be met:

(1) Compound all medications in one of the following environments:

(A) A separate controlled limited access area with a positive air flow room inspected and certified as meeting Class 10,000 requirements (Class 10,000 as defined by Federal Standard 209E).

(B) An enclosed room providing a Class 100 environment for compounding.

(C) A barrier isolator that provides a Class 100 environment for compounding.

It is recommended that all pharmacies have an anteroom designed to be separate from the buffer room. The anteroom should be available for the decontamination of supplies and equipment, and donning of protective apparel. A sink should be available in the anteroom area so that personnel can scrub prior to entering the buffer room.

(2) Use total aseptic techniques, including gowning, mask, and hair net. Scrubs may be worn, instead of gowning, if not worn or covered outside of the controlled limited access area.

(3) Provide a system for tracking each compounded product including:

(A) Personnel involved in each stage of compounding;

(B) Raw materials used including quantities, manufacturer, lot number, and expiration date;

(C) Labeling;

(D) Compounding records shall be kept for 2 years.

(4) Establishment of procedures for sterilization of all products prepared with any non-sterile ingredients by filtration with 0.22 micron or other means appropriate for the product components.

~~(5) Establishment of procedures for monitoring microbial growth. All sterile products compounded using non-sterile ingredients and prepared in large batch quantities in which no patient specific prescription exists shall have end product sterility testing required. Any positive sterility test results shall prompt an investigation of aseptic technique, environmental control, and other sterility assurance controls to identify and correct problems as much as possible.~~

(5)

(A) All high-risk level compounded sterile products for administration by injection into the vascular and central nervous systems that are prepared in groups of more than twenty-five (25) identical individual single-dose packages (such as ampules,

bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than twelve (12) hours at a two (2) to eight (8) degrees centigrade and longer than six (6) hours at warmer than eight (8) degrees centigrade before they are sterilized shall be tested to ensure they are sterile, do not contain excessive bacterial endotoxins, and are of labeled potency before they are dispensed or administered as provided below.

(B) Sterility Testing (Bacterial and Fungal) – The USP Membrane Filtration Method is the method of choice where feasible (e.g. components are compatible with the membrane). The USP Direct Transfer Method is preferred when the membrane filtration is not feasible. An alternative method may be used if verification results demonstrate that the alternative is at least as effective and reliable as the USP Membrane Filtration Method or the USP Direct Transfer Method. The pharmacist in charge shall establish written procedures requiring daily observation of the media and requiring an immediate recall if there is any evidence of microbial growth and said procedures must be available to Board inspectors.

(C) Bacterial Endotoxin (Pyrogen) Testing – The USP Bacterial Endotoxin Test, or verified equivalent, shall be used to ensure compounded sterile products do not contain excessive endotoxins.

(D) Potency Testing – The potency of all compounded products meeting the criteria described in Board regulation 07-02-0001 (j) (5) above must be tested to verify the potency stated on the label. Products for which there is no known or commercially available potency test standard require Board approval prior to compounding.

(E) The USP Membrane Filtration Method and the USP Direct Transfer Method are the membrane filtration and direct transfer methods described in Chapter 71,United States Pharmacopeia ("USP"), 2001 Edition. The USP Bacterial Endotoxin Test is the bacterial filtration test described in Chapter 85, USP, 2001 Edition. Should there be any amendment or change in any of the above methods or test by USP subsequent to the effective date of this paragraph, said change or amendment to USP shall be effective under this regulation after the expiration of thirty (30) days from the effective date of said change or amendment, unless within said time period, the Executive Director objects to said change or amendment. In that case, the Executive Director shall publish the reasons for objection and afford all interested parties an opportunity to present commentary; said notice and commentary shall be pursuant to A.C.A. § 25-15-204, as amended, and the resulting decision by the Board shall be reflected by an amendment to this regulation.

(6) Establishment of procedures for yearly testing the techniques of pharmacists using simulated aseptic procedures and documentation thereof.

(7) Any construction requirements as required by this regulation (i.e. separate controlled limited access area and certification of Class 10,000) must be complied with by January 2004. Adopted: 6/85 (Amended 8/2001, ~~and~~ 2/2003 & emergency 6/2003 & 10/2003).

07-02-0002—GOOD COMPOUNDING PRACTICES

(a) This regulation describes the requirements of minimum current good compounding practice for

the preparation of drug products by pharmacies or other facilities with permits issued by the Arkansas State Board of Pharmacy.

Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of a commercially available FDA-approved drug product is generally prohibited. However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available based on documentation provided by the prescribing physician of a patient specific medical need (e.g. the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The recommended methodology for documenting unavailability is to print the screen of wholesalers showing back-ordered, discontinued, or out-of-stock items. This or similar documentation must be available when requested by the Board.

(b) Definitions:

The following words or terms, when used in this regulation, shall have the following meaning, unless the context clearly indicates otherwise:

(1) "Compounding" means preparation, mixing, assembling, packaging, and labeling of a drug or device as the result of a duly authorized practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice.

(A) Compounding may also be for the purpose of, or as an incident to, research, teaching, or chemical analysis.

(B) Compounding includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(C) Reconstitution of commercial products is not considered compounding for the purposes of this regulation.

(2) "Component" means any ingredient used in the compounding of a drug product, including those that may not appear in such product.

(3) "Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substance(s) or labeling or re-labeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes any preparation of a drug or device that is given or sold for resale by pharmacies, practitioners, or other persons. The distribution of inordinate amounts of compounded products, without a practitioner/patient/pharmacist relationship is considered manufacturing.

(4) "Pharmacy generated products" means a medical product that is prepared, packaged, and labeled in a pharmacy that can be sold by the pharmacy without a prescription.

(c) Pharmacist responsibilities:

(1) All pharmacists, who engage in drug compounding, shall be proficient in compounding and shall continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature.

~~(2) Every pharmacist engaging in drug compounding must be familiar with all details of good compounding practices and should be familiar with Food and Drug Administration Modernization Act related patient regulation.~~

~~(3)~~ (2) The pharmacist has the responsibility to:

(A) Assure the validity of all prescriptions;

(B) Approve or reject all components, drug product containers, closures, in-process materials, and labeling;

(C) Prepare and review all compounding records and procedures to ensure that no errors have occurred in the compounding process;

(D) Ensure the proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice;

(E) Ensure only personnel authorized by the pharmacist in charge shall be in the immediate vicinity of the drug compounding operation.

(d) Drug compounding facilities:

(1) Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly compounding of prescriptions, including the placement of equipment and materials.

(2) The aseptic processing for sterile products shall be in an area separate and distinct from the area used for the compounding of non-sterile drug products.

(3) The area(s) used for the compounding of drugs shall be maintained in a good state of repair.

(4) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

(5) Adequate lighting and ventilation shall be provided in all compounding areas.

(6) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product.

(7) These area(s) used for compounding shall be maintained in a clean and sanitary condition.

(8) If parenteral products are being compounded, standards set out in Board Regulation 07-02-0001 must be met.

(e) Compounding equipment

(1) Equipment used in the compounding of drug products shall be of appropriate design and capacity as well as suitably located to facilitate operations for its intended use, cleaning, and maintenance.

(2) Compounding equipment shall be of suitable composition so the surfaces that contact components shall not be reactive, additive, or absorptive so as to alter the purity of the product compounded.

(3) Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination.

(4) Equipment and utensils must be stored in a manner to protect from contamination.

(5) Automated, mechanical, electronic, limited commercial scale manufacturing or testing equipment, and other types of equipment may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

(6) Immediately prior to the initiation of compounding operations, the equipment and utensils must be inspected by the pharmacist and determined to be suitable for use.

(7) When drug products with special precautions (antibiotics, hazardous materials and cytotoxins) are involved, appropriate measures must be utilized in order to prevent cross-contamination and proper disposal procedures must be followed. These measures include either the dedication of equipment for such operations or the meticulous cleaning of

equipment prior to its use for the preparation of other drugs.

(f) Component selection requirements:
  (1) Pharmacists shall first attempt to use United States Pharmacopoeia / The National Formulary (USP-NF) drug substances for compounding that have been made in ~~an~~ a Food and Drug Administration ~~inspected~~ registered facility.
  (2) If components are not obtainable from an FDA ~~inspected~~ registered facility of if the Food and Drug Administration and/or the company cannot document Food and Drug Administration ~~inspection~~ registered, pharmacists compounding prescriptions shall use their professional judgment in first receiving, storing, or using drug components that meet official compendia requirements or another high quality source.

(g) Control of drug products:
  (1) Drug product containers and closures shall be handled and stored in a manner to prevent contamination and to permit inspection and cleaning of the work area.
  (2) Containers and closures shall be suitable material as to not alter the compounded drug as to quality, strength, or purity.

(h) Drug compounding controls:
  (1) There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality and purity they purport or are represented to possess.
  (2) Procedures shall include a listing of the components, their amounts (in weight or volume), the order of component mixing, and a description of the compounding process.
  (3) All equipment and utensils and the container/closure system relevant to the sterility and stability of the intended use of the drug shall be listed.
  (4) All written procedures shall be followed in the execution of the compounding procedure.
  (5) Components shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight and measure is correct as stated in the written compounding procedures.
  (6) Written procedures shall be established and followed that describe the tests or examination to be conducted on the product compounded (e.g. degree of weight variation among capsules) to ensure reasonable uniformity and integrity of compounded drug products.
    (A) Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product.
    (B) Such control procedures shall include, but are not limited to, the following (where appropriate):
      (i) capsule weight variation;
      (ii) adequacy of mixing to assure uniformity and homogeneity; and
      (iii) clarity, completeness or pH of solutions.
  (7) Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall follow accepted standards of practice and/or include validation of any sterilization process.
  (8) Beyond use dates and storage requirements (e.g. refrigeration) should be established. The USP-NF guidelines should be used.

(i) Labeling:

(1) If a component is transferred from the original container to another (e.g. a powder is taken from the original container, weighed, placed in a container) and stored in another container, the new container shall be identified with the:
(A) component name;
(B) lot and expiration date if available;
(C) strength and concentration;
(D) weight or measure; and
(E) route of administration

(2) Products prepared in anticipation of a prescription prior to receiving a valid prescription should not be an inordinate amount.
(A) A regularly used amount should be prepared based on a history of prescriptions filled by the pharmacy.
(B) These products shall be labeled or documentation referenced with the:
(i) complete list of ingredients or preparation name and reference;
(ii) federal expiration date—up to one (1) year;
(iii) assigned beyond –use date:
(a) based on published data, or;
(b) appropriate testing, or;
(c) USP-NF standards.
(iv) storage under conditions dictated by its composition and stability (e.g., in a clean, dry place or in the refrigerator); and
(v) batch or lot number.
(A) Upon the completion of the drug preparation operation, the pharmacist shall examine the product for correct labeling.
(B) The prescription label shall contain the following:
(i) patient name;
(ii) prescriber's name;
(iii) name and address of pharmacy;
(iv) directions for use;
(v) date filled;
(vi) beyond use date and storage (may be auxiliary labels); and
(vii) an appropriate designation that this is a compounded prescription, with reference to active ingredients.

(j) Records and Reports:
(1) Any procedures or other records required to comply with good compounding practices shall be retained for the same period of time as required for retention of prescription records.
(2) All records required to be retained under good compounding practices, or copies of such records, shall be readily available for authorized inspection.
(3) Computer information and the hard copy of the prescription should indicate that the prescription is to be compounded.
(4) Adequate records must be kept of controlled substances (Scheduled drugs) used in compounding.

(k) Pharmacy generated product requirements:
(1) A pharmacy generated product (PGP) may be prepared from legend drugs, not to exceed recommended strengths and doses.
(2) PGP will be labeled properly and will be sold with the public's health and welfare in mind.

(3) A PGP cannot be bulk compounded to sell to a second entity for resale. This would require a manufacturer's permit.

(l) Compounding for a prescriber's office use:

(1) Pharmacies may prepare compounded drug products for a duly authorized prescriber's office use.

(2) An order by the duly authorized prescriber, indicating the formula and quantity ordered, will be filed in the pharmacy.

(3) The product is to be administered in the office and not dispensed to the patient. The product shall be labeled "For Office Use Only—Not for Resale".

(4) A record of the compounded drug product may be kept as a prescription record in the pharmacy computer.

(5) A label may be generated and a number assigned by the pharmacy computer for the compounded drug product.

(6) Patient specific prescriptions for controlled substances cannot be filled "for office or medical bag use".

(7) A retail pharmacy is not precluded from making more that five percent (5%) of its annual sales to licensed practitioners. The pharmacy must, however, obtain a State Wholesale Legend Drug and/or Controlled Substance Distributor Permit.

(m) Compounding veterinarian products:

(1) Prescriptions for animals may be compounded based on an order or prescription from a duly authorized prescriber.

(2) These prescriptions are to be handled and filled the same as the human prescriptions.

~~(3) Caution should be taken as to not violate federal patent laws by duplicating an available product in inordinate quantities.~~

~~(4)~~ (3) Patient specific prescriptions for controlled substances cannot be filled "for office or medical bag use".

(4) Compounding for office stock for veterinarians is prohibited, except for compounds to be used in life-threatening situations where lack of immediate availability of the product could result in patient harm and no FDA-approved product is commercially available. (Adopted 2/2001, Revised emergency 6/2003 & 10/2003)

07-03: SAMPLES

07-03-0001—DRUG SAMPLES

(a) Definitions

(1) "Drug sample" means a unit of a legend drug which is distributed to a practitioner by a manufacturer or a manufacturer's representative at no charge, is not intended to be sold, and is intended to promote the sale of the drug. "Drug sample" shall not mean a drug under clinical investigations approved by the federal Food and Drug Administration.

(2) "Coupon" means a form which may be redeemed as part of, or all of, the cost of a prescription for a legend drug after it has been dispensed.

(3) "Legend Drug" means a drug limited by Section 503 (b)(1) of the Federal Food, Drug, and Cosmetic Act to being dispensed by or upon a medical practitioner's prescription because the drug is (a) habit forming, (b) toxic or having potential for harm, or (c) the new drug application for the drug limits its use to use under a practitioner's supervision. The product label of which is required to contain the statement "CAUTION, FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION."